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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,343	03/18/2005	Yoshiaki Isobe	0020-5350PUS1	5054

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EXAMINER
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BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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01/24/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,343	<b>Applicant(s)</b> ISOBE ET AL.	
	<b>Examiner</b> /Mark L. Berch/	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: ____.                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/18/2005;06/16/2005; 04/03/2007.

### **DETAILED ACTION**

**The restriction requirement is modified to combine Groups I and IV.**

**Claims 77-84, 88 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction.**

**This does not constitute an art recognized genus. Because of the marked structural differences at a part of the molecule essential for utility, the claims are deemed to lack unity of invention (see *In re Harnish*, 206 USPQ 300). The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter (removal of viral and dermal) will overcome the rejection.**

#### ***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 47-50, 54, 57, 67-84, are 87-88 are rejected under 35 U.S.C. 102(b) as being anticipated by 6329381.**

#### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

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Claims 47-50, 54, 57, 67-84, are 87-88 are under 35 U.S.C. 103(a) as being unpatentable over 6329381.

See Formula I in general, and examples 39-40, with Q1 as COOMethyl and example 45, with Q1 as CONH<sub>2</sub>, with the 9-position having unsubstituted benzyl in each case, X1=S, Y1 as methylene or ethylene or propylene. A transdermal formulation is disclosed at column 20, line 40. A transdermal formulation meets the claim language, as it is applied directly to the skin. Further, line 40 mentions propellants, which are used only in sprays, which again falls into the claim 47 claim language. Accordingly, all elements of the claims are disclosed, and the claims are anticipated.

Alternatively, it would be obvious to prepare such compositions, as that is exactly what the specification teaches, even if no specific formulations are set forth.

The utility of the compounds is generally the same.

Certain claims, e.g. claim 70 recite a physiological property. This exact property does not appear in the reference. MPEP 2112 states:

**“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY**

**The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”**

In this case, the “unknown property” is the e.g. half life. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

**“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC**

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Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is the half-life.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. In every reference applied, the reference explicitly teaches exactly what the compound is. In fact, it is the opposite. In a normal inherency situation, the claim is of known structure, and the reference is of unknown structure. Here, the reverse is true, and hence the legal circumstances of inherency-in-the-prior-art do not apply. The only difference is the property about which the reference happens to be silent. Recitation of a property, inherently possessed by the prior art thing, does not distinguish a claim drawn to those things from the prior art, *In re Swinehart*, 169 USPQ 226, 229.

See for example *Ex parte Anderson*, 21 USPQ 2d 1241 at 1251, discussion of Rejection E. The claims had “numerical or functional values for certain properties which [the authors of the references] did not measure”. The PTO presented no reasoning as to why the prior art material would have been expected to have those properties. Instead, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253).

In another example, certain claims of *Ex parte Raychem Corp.* 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: “However, this does not end the inquiry since, where the Patent

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and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists....”

And indeed, there have been a number of cases in which applicants have pointed to silence of the prior art with regard to this or that property: *In re Pearson*, 181 USPQ 641; *In re Zierden* 162 USPQ 102; *In re Lemin*, 140 USPQ 273; *Titanium Metals Corporation of America v. Banner*, 227 USPQ 773; *In re Benner*, 82 USPQ 49; *In re Wilder*, 166 USPQ 545; *Ex parte Kucera*, 165 USPQ 332; *General Electric Co. v. Jewel Incandescent Lamp Co.*, 67 USPQ 155; *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607; *In re Parker*, 43 USPQ 457. Such efforts to avoid anticipation on that basis invariably failed. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see *In re Schoenwald*, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, or ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**Claims 47-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

- 1. The definition of Q1 appears twice and this is confusing. It is suggested that the first appearance be prefaced with “when m is 1 or 2”.**
- 2. A proper composition claim must have a carrier of some kind; otherwise it is identical with a compound claim. Adding a carrier will resolve the matter.**
- 3. Claim 58 cannot depend on claim 47, as a composition claim is narrower than a compound claim.**
- 4. Claim 65 fails to define Formula 1. Note that this is an independent claim.**
- 5. Claim 70 is indefinite. There is no way of telling how this measurement must be done. It is not clear even what type of serum is intended. The word can refer to any kind of clear bodily fluid. Even if it refers to blood plasma, with clotting factors removed, different types of blood can vary in pH, etc.**
- 6. The reference to “lever S9” in claim 71 is surely wrong.**
- 7. Likewise, the “inhalation” of claim 84 must be wrong as well. This is a “topically administrable medicament”.**



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**Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**There is two problems here. First, the procedure is unclear. Topically applied where and to what species? What dose is involved?**

**Second, the term “interferon” is incomplete; there is no such thing per se, but there is rather a large family of somewhat related species. These fall into 3 major classes:**

**A. Type I IFNs consists of 13 different alpha-IFN isoforms (leukocyte interferon), a single beta-IFN (fibroblast interferon), an omega-IFN , an epsilon-IFN and a kappa-IFN. In addition, IFN-zeta (limitin) is found in mice, IFN-nu in cats, IFN-tau in ruminants and IFN-delta in pigs has been identified.**

**B. The type II IFNs consists just of IFN-gamma (immune interferon).**

**C. The Type III is IFN-lambda with 3 different isoforms, and was only recently discovered (2003).**

**These operate via multiple signaling mechanisms, and bind at different places. Type I binds at a cell surface receptor complex consisting of IFNAR1 and IFNAR2 chains, while Type II binds to a complex, which is made up of IFNGR1 and IFNGR2 subunits and Type III uses complex consisting of IL10R2 and IFNLR1. These also have different origins. Interferon-alpha is produced in leukocytes, Interferon-beta is produced in fibroblasts, or in epithelial cells, and Interferon-gamma is produced in certain activated T-cells and NK cells. The gene encoding IFN-kappa is expressed in epidermal keratinocytes. IFN-tau is produced in trophoblasts.**

**The specification gives no specific teaching on this subject.**

**Claims 74-77, 79-84, 87-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or**

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with which it is most nearly connected, to make and/or use the invention. Such a utility cannot be deemed enabled. .

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is “undue”; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

**(1) Breadth of claims.**

**(a) Scope of the compounds.** Because of the broad scope of Q1, Q2, A and Y2, trillions of compounds are covered.

**(b) Scope of the diseases covered.**

A. Regulating immune response is embrative of treating autoimmune disorders. The “autoimmune diseases” are processes that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There are dozens of such diseases, which have fundamentally different mechanisms and different underlying causes. Known autoimmune disorders, or disorders generally considered to be autoimmune include Polymyositis, Scleroderma, Autoimmune polyendocrinopathy-candidiasis-ectodermal dystrophy (APECED), Meniere's disease, Omenn syndrome, Idiopathic neutropenia, Idiopathic thrombocytopenic purpura, Autoimmune hemolytic anemia, Premature ovarian failure, Idiopathic hypoparathyroidism, primary biliary cirrhosis,

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**Pemphigus, multiple sclerosis, autoimmune uveitis, rheumatoid arthritis, Addison's disease, Silent thyroiditis, atrophic gastritis, myasthenia gravis, idiopathic thrombocytopenic purpura, thrombotic thrombocytopenic purpura, hemolytic anemia, systemic lupus erythematosus, Wegener's granulomatosis, polyarteritis nodosa, erythema nodosum leprosum, Guillain-Barré syndrome (GBS), allergic encephalomyelitis, acute necrotizing hemorrhagic encephalopathy, idiopathic bilateral progressive sensorineural hearing loss (IPBSNHL), aplastic anemia, pure red cell anemia, polychondritis, scleroderma, Stevens-Johnson syndrome, Alopecia areata, asthma, idiopathic sprue, lichen planus, Crohn's disease, Graves ophthalmopathy, sarcoidosis, primary biliary cirrhosis, type I diabetes, autoimmune optic neuritis, uveitis posterior, or interstitial lung fibrosis, Reiter's syndrome, Sjögren's Syndrome, Goodpasture Syndrome, inflammatory bowel disease, Essential Mixed Cryoglobulinemia, Behçet's Syndrome, Chronic Inflammatory Polyneuritis (CIPD), CREST Syndrome, Antiphospholipid Syndrome, Relapsing Polychondritis (systemic chondromalacia or von Meyenburg disease), Retroperitoneal Fibrosis, Celiac disease, Vitiligo, "immune dysregulation, polyendocrinopathy, enteropathy, X-linked syndrome" (IPEX), Autoimmune Atherosclerosis and many more.**

**B. It also covers the treatment of allergies, which is set forth specifically in clms 77-84 and 88. The term "allergies", "allergic diseases" and the like are fairly broad, and are used in somewhat different ways by different people, and as a result, it is not always clear what the term denotes.**

**There are four major categories that are normally included:**

- A. Atopic IgE mediated, e.g. eczema, allergic rhinitis and most forms of asthma**
- B. Non-atopic IgE mediated, including reactions to insect and spider bites, and reactions to certain drugs**
- C. IgG mediated, e.g. allergies to casein and other milk proteins, and gluten. (Type III Hypersensitivity)**

**D. T-cell mediated allergies, including poison ivy, nickel contact dermatitis, other forms of Allergic contact dermatitis. (Type IV Hypersensitivity, also called cell-mediated or delayed-type hypersensitivity, DTH).**

**Other types of reactions may or may not be considered as allergies. Thus, type II hypersensitivity, a cytotoxic reactions which involves IgM or IgG or both, including e.g. ABO incompatibility reaction, Rhesus disease may or may not be considered an allergy reaction. It is unclear whether aspirin sensitivity is an allergy or an intolerance. Whether there is such a thing as fluoride allergy is contested. Some consider all reaction to ordinary food additives as intolerance, but others believe that some of these are in fact allergic reactions.**

**C. “Regulating” would also include the opposite effect, where the cellular and/or humoral immune system is stimulated to cope with immunodeficiency arising from irradiation, chemotherapy, HIV, genetic disorders, age-associated damage etc. There are a significant number of Immunodeficiency Disorders, in two very different categories. Primary Immunodeficiency disorders are caused by inherited functional defects in the cells of the immune system, particularly B and/or T Lymphocytes. Examples include X-linked Agammaglobulinemia (Bruton's disease), Common Variable Immunodeficiency, Selective IgA Deficiency, DiGeorge Syndrome, Severe Combined Immunodeficiency Disease (SCID, which is actually heterogeneous group of conditions all associated with genetic defects in those lymphoid stem cells that are precursors for both T and B Lymphocytes. This causes functional impairment of both humoral and cell-mediated immunity), Wiskott-Aldrich syndrome, Ataxia-Telangiectasia, and other inherited defects in the complement system, and defects in granulocyte function. Secondary immunodeficiencies are acquired defects in immune function resulting from a wide variety of sources. These include drugs (e.g. cancer chemotherapeutic agents, Cyclosporin, and corticosteroids), infections of immune system cells (most notably HIV), disseminated cancers (malignancies that invade the bone marrow may crowd**

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out immune system cells and their precursors), malnutrition, radiation therapy (bone marrow suppression, lymphocyte toxicity), Splenectomy (increased susceptibility to infection by encapsulated microorganisms), severe burns (loss of immunoglobulins through damaged skin) and chronic renal disease.

(2) The nature of the invention and predictability in the art: The invention is directed toward medicine and is therefore physiological in nature. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved,” and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(3) Direction or Guidance: That provided is very limited. The dosage range information provided for external administration appears only in the last full sentence on page 43. However, this does not give any amounts, any daily dosage, just a broad concentration range. Further, it is completely generic. That is, it is the same dosage for all disorders listed in the specification, which is a very substantial range of disorders.

(4) State of the Prior Art: The compounds are 8-hydroxy adenines with a particular substitution patters in the 2-position and 9-position. So far as the examiner is aware, no 8-hydroxy adenines of any kind at all are presently in use for the treatment of any immune-oriented disorder.

(5) Working Examples: There are no working examples to the treatment of any actual disorder. Examples 122 and 123 provide an in vitro test showing the stimulation of the production of an aunspecified type of interferon. Example 126 shows the nasal administration to an asthma-model mouse, showing the one compound tested to be somewhat less effective that Beclometasone dipropionate.

(6) Skill of those in the art: This very much depends on the particular art area. In fact, there are four basic mechanisms underlying autoimmune disease: 1. Antibody mediated diseases: a specific

antibody exists targeted against a particular antigen (protein), which leads to its destruction and signs of the disease. Examples are: auto-immune mediated hemolytic anemia, where the target is on the surface of the red blood cell; myasthenia gravis where the target is the acetylcholine receptor in the neuromuscular junction; hypoadrenocorticism (Addison's) where the targets are the cells of the adrenal gland. 2. Immune-complex-mediated diseases: antibodies are produced against proteins in the body. These combine into large molecules that circulate around the body. In systemic lupus erythematosus (SLE) antibodies are formed against several components in the cell's nucleus (hence the anti-nuclear antibody test (ANA) for SLE). Most notably antibodies are made against the body's double stranded DNA, and form circulating soluble complexes of DNA and antibody, which break down in skin causing an increased sensitivity to ultraviolet light and a variety of signs. As the blood is filtered through the kidneys, the complexes are trapped in the glomeruli and blood vessels, causing the kidney to leak protein - glomerulonephritis. They also cause leakage in other blood vessels, and there may be hemorrhaging, as well as accumulating in synovial fluid and causing signs of arthritis and joint pain. Rheumatoid arthritis results from immune complexes (IgM class antibody called rheumatoid factor) against part of the patient's own immune system (part of its IgG molecules). These form complexes that are deposited in the synovia of the joint spaces causing an inflammatory response, joint swelling, and pain. The collagen and cartilage of the joint breaks down and is eventually replaced by fibrin which fuses the joints - ankylosis. 3. Antibody and T Cell-mediated diseases: T cells are one of two types (the other being B-cells), which mediate immune reactions. Upon exposure to a particular antigen, they become programmed to search for and destroy that particular protein in future. Once a patient has been exposed to an antigen, he will be able to mount a much faster response to it the next time it encounters it. This is the basis of vaccination. Thyroiditis (autoimmune hypothyroidism) seems to be of mixed etiology. Several target antigens have been identified, including thyroglobulin the major hormone made by the

thyroid. Auto-antibodies to antigens in the epithelial cells of the thyroid have also been found. The thyroid becomes invaded by large numbers of T and B cells as well as macrophages, which are cells that engulf and destroy other cell types. T cells specifically programmed for thyroglobulin have been identified. Autoimmune disorders can arise from the killer T-cells, from the helper T-cells, or from the regulatory T-cells (e.g. IPEX syndrome). 4. Diseases arising from a deficiency in complement: When an antigen and antibody react they may activate a series of serum enzymes (the complement system) whose end result is either the lysis (breakup) of the antigen molecule or to make it easier for phagocytic cells like the macrophages to destroy it. Patients with deficiencies in enzymes activated early in the complement system develop autoimmune diseases like SLE. Thus, with such differing mechanisms, it is not logical that a treatment for autoimmune diseases generally can be found.

Examples of pharmaceutically untreatable autoimmune disorders include celiac disease, APECED, and ALS. Medicines can be given to relieve symptoms, e.g. replace missing hormones or ameliorate pain, but these pharmaceuticals do not treat the disease itself.

Basically, there are two immune system, cell and humoral, and the claims cover both increasing and decreasing both of them, i.e. four different effects. Further, there are many different regulators involved, including two different types of T-cells, IgE, IgM, IgG, B cells and others. Such a scope cannot possibly be deemed enabled.

(7) The quantity of experimentation needed: Especially in view of points 1, 4, 5 and 6, the amount is expected to be high.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention

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without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion is clearly justified here.

Note that claim 78 is not included in the above rejection.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-55, 57-61, 63-88 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 21 of copending Application No. 10594074. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is substantial overlap when in 10528343, m=1. For example, the species 9-(3-carboxymethylbenzyl)-2-(2-ethoxyethoxy)-8-hydroxyadenine of 10594074 falls within the claims of 10528343 for m=1, Y2=methylene, and Q1=alkoxy.

7157465 is noted, which has claims embrative of these, but no species appears which anticipates or renders obvious the claims here.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



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**In the event applicants corresponding to WO 2007034917, WO 2007034817 or JP 2005089334 are filed with the PTO, applicants are to inform the examiner of this.**

**Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.**

**Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.**

**/Mark L. Berch/  
Primary Examiner  
Art Unit 1624**

**1/22/2008**